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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,293

11/17/2003

Stephen P. Massia

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EXAMINER

NIEBAUER, RONALD T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/716,293	Applicant(s) MASSIA ET AL.	
	Examiner RONALD T. NIEBAUER	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,10-20,25,26,31-46 and 101-105 is/are pending in the application.
- 4a) Of the above claim(s) 10-20,25,26,31-46 and 101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 102-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments and arguments filed 5/7/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. In particular, due to applicants amendments the previous 112,102, and 103 rejections are withdrawn.

Claims 2-9,21-24,27-30,47-100 have been cancelled. Claims 1,10-20 have been amended. Claims 102-105 have been added as new claims.

After first office action was issued (1/7/08) applicant submitted an IDS (2/19/08). The IDS necessitates a new ground of rejection (see MPEP section 609.04(b) II A2). In particular, art from the IDS reads on the elected species (SEQ ID NO:124). As such, no claims are allowable. Any art found in the course of searching for elected species is also cited herein.

Applicant states (page 10 of reply dated 5/7/08) that claims 10-20,25-26,31-46,101 are withdrawn. Claims 10-20,25-26,31-46,101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim.

Claim 1,102-105 are under consideration.

Claim Objections

This objection is a new objection necessitated by applicants amendment and addition of new claims.

Applicant is advised that should claim 103 be found allowable, claim 105 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case, claim 103 is drawn to a therapeutic bioconjugate comprising a polysaccharide and a peptide comprising SEQ ID NO:124. Claim 105 is also drawn to a therapeutic bioconjugate comprising a polysaccharide and a peptide comprising SEQ ID NO:124. As such, the claims cover the same scope.

Claim Rejections - 35 USC § 102

This rejection is necessitated by necessitated by applicants submission of an IDS (see MPEP 609.04(b) II A2).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1,102-105 are rejected under 35 U.S.C. 102(a) as being anticipated by Kalstad et al. (Proceedings of the Second Joint EMBS/BMES Conference Oct 23-26, 2002 as cited in IDS).

Kalstad teach (page 736 first column last paragraph) that the peptide CNAFKILVVITDGEK was conjugated with dextran. The peptide CNAFKILVVITDGEK is

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identical to SEQ ID NO:124 of the instant invention. As such, the peptide CNAFKILVVITDGEK conjugated with dextran meets the limitations of claims 1,102-105 of the instant invention. It is noted that claim 104 states that dextran is a polysaccharide and as such the limitations of claims 103,105 are met.

It is noted that Kalstad et al. is 'by another' since the publication lists Kalstad and Panitch as two of the co-authors. It is noted that the instant application is a CIP of 10/295,734 (11/15/02). 10/295,734 does provide support for the elected species (SEQ ID NO:124) conjugated to dextran (page 17 last paragraph of 10/295,734; original claim 7), as well as support for hydrophilic polymers (page 9 past paragraph of 10/295,734) and polysaccharides (page 5 1st paragraph of 10/295,734).

This rejection is a new rejection necessitated by applicants submission of an IDS (see MPEP 609.04(b) II A2).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kalstad et al. (Proceedings of the Second Joint EMBS/BMES Conference Oct 23-26, 2002 as cited in IDS).

Kalstad teach (page 736 first column last paragraph) that the peptide CNAFKILVVITDGEK was conjugated with dextran. The peptide CNAFKILVVITDGEK is

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identical to SEQ ID NO:124 of the instant invention. As such, the peptide CNAFKILVVITDGEK conjugated with dextran meets the limitations of claim 1 of the instant invention.

It is noted that the instant application is a CIP of 10/295,734 (11/15/02). 10/295,734 does provide support for the elected species conjugated to dextran (page 17 last paragraph of 10/295,734; original claim 7), as well as support for hydrophilic polymers (page 9 past paragraph of 10/295,734) and polysaccharides (page 5 1st paragraph of 10/295,734). However, instant claim 1 recites that the peptides can be selected from the group consisting of SEQ ID NO:2,4,6,8,etc. However, SEQ ID NO:1,4,6,8, for example, of the instant invention are not supported by 10/295,734 (11/15/02). As such, the priority date of claim 1 of the instant invention is 11/17/03. It is noted that claims can not be given support in part for particular species. 10/295,734 only provides support for the peptide CNAFKILVVITDGEK (SEQ ID NO:124 of the instant invention). 10/295,734 does not recite TYKTKEEMIVATSQTSQY (SEQ ID NO:2 of the instant invention) for example. As such, Kalstad et al. is a proper 102(b) reference.

This rejection is a new rejection necessitated by applicants amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tuckwell et al. (Journal of Cell Science 1995 v108 pages 1629-1637; will be referred to as Tuckwell 1995) as evidenced by Tuckwell et al. (Biochem J. 2000 v350 pages 485-493 as cited in IDS; will be referred to as Tuckwell 2000).

Tuckwell 1995 teach (abstract) recombinant human alpha2 I-domain (alpha2I) constructs (abstract). Tuckwell 1995 teach the generation of the constructs (page 1630 first paragraph). Tuckwell 1995 teach that a glutathione S-transferase alpha2I fusion protein was expressed (page 1630 first paragraph last sentence).

Tuckwell 2000 also teach the glutathione S-transferase alpha2I fusion protein (page 486, 2nd complete paragraph). Tuckwell 2000 teach that the sequence of the protein includes (Figure 7) TYKTK EEMIVATSQTSQY which is SEQ ID NO:2 of the instant invention.

Tuckwell 2000 is cited to verify that the recombinant human alpha2 I-domain that is discussed in Tuckwell 1995 does in fact comprise SEQ ID NO:2 of the instant invention.

It is noted that the instant claim is drawn to a bioconjugate comprising elements (a) and (b). Glutathione S transferase is a peptide which is a polymer of amino acids. Further, the protein is regarded as a hydrophilic polymer as recited in claim 1a. The peptide of Tuckwell comprises SEQ ID NO:2 as recited in claim 1b. Since the Glutathione S transferase and recombinant human alpha2 I-domain are fused together they meet the limitation of being a conjugate as recited in instant claim 1.

Double Patenting

The previous double patenting rejection involving application 11/244,536 has been withdrawn since application 11/244,536 has been abandoned.

Conclusion

Applicant's amendment necessitated a new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/19/08 prompted a new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/
Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654